ENVIRONMENTAL WORKING GROUP

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December 23, 2004

Linda M. Katz, M.D., M.P.H.
Director
Office of Cosmetics and Colors
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Docket No. 2004P-0266/CP1

Dear Dr. Katz:

Environmental Working Group and Olivia James filed a petition with your office seeking Food and Drug Administration (FDA) action to immediately cease the unlawful distribution of misbranded, adulterated and unlabeled cosmetics on June 14, 2004. On December 14, 2004, you issued a letter stating that your office will not comply with the 180-day response deadline for responding to citizen petitions set forth in Food and Drug Administration General Administrative Procedures, 21 C.F.R. § 10.30(e)(2). Your letter has not provided an estimated final response date or an explanation of the reason for the delay. In light of the important public health implications of the presence of untested chemicals in everyday cosmetic products, we are eager to obtain a final determination on the petition. We respectfully request further information regarding the reason for the delay in responding to the petition and the estimated final response date.

Because of your failure to respond to our petition, major cosmetics manufacturers, including Estée Lauder, continue to advertise cosmetic products for sale on the internet without providing a detailed listing of ingredients prior to purchase as required by FDA regulations. *See* 21 CFR § 701.2-3. Estée Lauder is one of the world's leading manufacturers and marketers of skin care, makeup, fragrance and hair care products, selling $5.79 billion worth of cosmetics under 22 different brand names in 2004. The company sells products to millions of Americans, and considering the sheer size of its market share, its practices effectively set the industry standard. EWG has identified the following Estee Lauder websites that continue to operate in apparent violation of this requirement:

1. www.clinique.com
2. www.aveda.com (lists only "key ingredients")
3. www.origins.com

We respectfully request response on the following specific issues:

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1. Why has FDA failed to respond to our petition within the 180-day response deadline for responding to citizen petitions set forth in Food and Drug Administration General Administrative Procedures, 21 C.F.R. § 10.30(e)(2), and when does the Agency intend to respond to each of the issues raised in our petition?
2. Will FDA issue guidance to the cosmetics industry on what constitutes a "safe" cosmetic, and how that safety must be substantiated? As you know, federal law requires that cosmetics be adequately substantiated for safety prior to marketing, but the cosmetics industry itself is left with the responsibility of interpreting the meaning of "safe," and deciding what if any studies must be done to "substantiate" safety. When will FDA issue guidance to industry on this critical public health issue?
3. When will FDA demand that Internet vendors, like Estée Lauder, to display product ingredient lists on websites selling products, as required by federal law?

Every day that the FDA allows violations of its safety standards to continue, the health of Americans is placed at an unnecessary risk of harm. We ask that you take immediate action to protect consumers by fully enforcing the laws that your agency is charged with implementing.

Please do not hesitate to contact us at (202) 667-6982 if you have any questions or need any further information on the petition. Thank you, in advance, for your assistance in this matter.

Sincerely Yours,

Jane Houlihan
Vice President for Research

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General Counsel

cc:

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